

IN THE CLAIMS

This listing of claims will replace all prior versions and listing of claims in the application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

1. (Currently amended) A method of treating, ~~preventing~~ or reducing the risk of developing a depressive disorder in a subject in need thereof, comprising the steps of:
~~administering a depressive disorder effective amount of a composition to an area of skin of the subject for delivery of a steroid in the testosterone synthetic pathway to blood serum of the subject, wherein the composition comprises:~~

(a) providing a pharmaceutical composition comprising:

(i) about 1% 0.01% to about 70% of the steroid in the testosterone synthetic pathway;

(b) ~~—~~(ii) about 0.01% to about 5[0]% penetration enhancing agent isopropyl myristate ;

(c) ~~—~~(iii) about 0.01% to about 5[0]% thickening agent; and.

(d) ~~—~~(iv) about 30 45% to about 98 90% lower alcohol; and

(v) water in an amount sufficient to total 100%

wherein the percentages are on a weight-to-weight basis of the composition; and

(b) administering a therapeutically effective amount of the composition to an area of skin of the subject in a single daily dose sufficient for delivery of the testosterone to the blood stream of the subject,

wherein the serum testosterone concentration is substantially maintained between about 300 ng testosterone per dL to about 1050 ng testosterone per dL, wherein the composition is

~~capable of releasing the steroid after applying the composition to the skin at a rate and duration that delivers at least about 10 µg per day of the steroid to the blood serum of the subject; and the percentages are on a weight to weight basis of the composition.~~

2. (Cancelled)
3. (Cancelled)
4. (Cancelled)
5. (Cancelled)
6. (Currently amended) The method of claim 1[2], wherein the thickening agent comprises about 0.1% to about 5% polyacrylic acid.
7. (Original) The method of claim 6, wherein the thickening agent comprises about 0.9 % polyacrylic acid.
8. (Original) The method of claim 6, wherein the polyacrylic acid is carboxypolyniethylene.
9. (Currently amended) The method of claim 1[2], wherein the lower alcohol comprises about ~~45-72.5%~~ 72.5% to about 90% ethanol or isopropanol.
10. (Cancelled)
11. (Currently amended) The method of claim 1[2], wherein the composition weighs equal to or less than about 100 grams.
12. (Currently amended) The method of claim 1[2], wherein the composition weighs about 1.0 grams to about 10 grams.
13. (Currently amended) The method of claim 1[2] wherein the composition weighs about 2.5 grams to about 7.5 grams.
14. (Currently amended) The method of claim 1[2], wherein the composition weighs about 5.0 grams.

15. (Currently amended) The method of claim 1[2], wherein the composition is capable of releasing the testosterone after applying the composition to the skin at a rate and duration that achieves circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

16. (Original) The method of claim 15, wherein the serum testosterone concentration is maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum.

17. (Currently amended) The method of claim 1[2], wherein for each about 0.1 gram per day application of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

18. (Currently amended) The method of claim 1[2], wherein the composition is provided to the subject for daily administration in about a 0.1 g to about a 10g dose.

19. (Cancelled)

20. (Cancelled)

21. (Cancelled)

22. (Currently amended) The method of claim 1[2], wherein the composition is provided to the subject in one or more packets.

23. (Original) The method of claim 22, wherein the packet comprises a polyethylene liner between the composition and inner surface of the packet.

24. (Currently amended) The method of claim 1[2], wherein the composition is provided as a separate component to a kit.

25. (Currently amended) The method of claim 1[2], wherein the subject has a pretreatment serum testosterone concentration less than about 300 ng/dl.

26. (Original) The method of claim 25, wherein after at least about 30 days of daily administration serum testosterone concentration in the subject is at least about 490 ng/dl to about 860 ng/dl.

27. (Original) The method of claim 25, wherein after at least about 30 days of daily administration total serum androgen concentration in the subject is greater than about 372 ng/dl.

28. (Currently amended) The method of claim 1[2], wherein the composition is administered ~~once, twice, or three times daily~~ for at least about 7 days.

29. (Cancelled)

30. (Cancelled)

31. (Cancelled)

32. (Cancelled)

33. (Cancelled)

34. (Cancelled)

35. (Cancelled)

36. (Cancelled)

37. (Cancelled)

38. (Cancelled)

39. (Cancelled)

40. (Cancelled)

41. (Cancelled)

42. (Cancelled)